



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **L. Gordon LETTS et al**

Application No: **10/718,060**

Group Art Unit: **1614**

Filed: **June 10, 2003**

Examiner: **Not yet assigned**

For: **Nitrosated and/or Nitrosylated Cyclooxygenase-2 Selective Inhibitors,
Compositions and Methods of Uses**

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C. F. R. §§1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form.

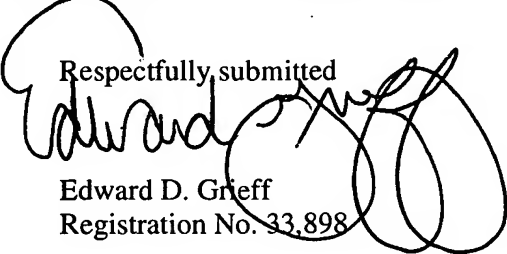
The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents are material to patentability or that the listed documents are prior art.

A copy of the documents listed on the attached PTO-1449 form is submitted herewith. The references listed on Sheet No. 9 of Form PTO-1449 were cited in the prosecution of the corresponding PCT patent application. A copy of each of the references and the search report for the PCT patent application are enclosed.

This Information Disclosure Statement is being submitted before a first office action. No fee is believed to be due; however, the Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219 to maintain the pendency of the present application.

Applicants respectfully request that the Examiner initial and return a copy of the enclosed PTO-1449 form with the next communication from the Patent Office.

Respectfully submitted


Edward D. Grief
Registration No. 33,898

Date: March 2, 2004
HALE and DORR LLP
1455 Pennsylvania Avenue, NW
Washington, DC 20004
Phone: (202) 942-8490
Fax: (202) 942-8484

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PTO/SB/08A (08-00)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 9

Complete if Known

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| Application Number | 10/718,060 |
| Filing Date | 6/10/03 |
| First Named Inventor | Letts et al |
| Group Art Unit | not yet assigned |
| Examiner Name | not yet assigned |
| Attorney Docket Number | 102258.157 US1 |

U.S. PATENT DOCUMENTS

| Examiner Initials ¹ | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-----------------------------------|--------------------------|----------------------|--------------------------------------|--|--|--|
| | | Number | Kind Code ² (if known) | | | |
| | | 5,621,000 | | Arena et al | 04-15-1997 | |
| | | 5,700,947 | | Del Soldato | 12-23-1997 | |
| | | 5,703,073 | | Garvey et al | 12-30-1997 | |
| | | 5,780,495 | | Del Soldato | 07-14-1998 | |
| | | 5,861,426 | | Del Soldato et al | 01-19-1999 | |
| | | 6,040,341 | | Del Soldato et al | 03-21-2000 | |
| | | 6,043,233 | | Garvey et al | 03-28-2000 | |
| | | 6,048,858 | | Garvey et al | 04-11-2000 | |
| | | 6,057,347 | | Garvey et al | 05-02-2000 | |
| | | 6,083,515 | | Garvey et al | 07-04-2000 | |
| | | 6,143,734 | | Garvey et al | 11-07-2000 | |
| | | 6,297,260 | | Bandarage et al | 01-02-2001 | |
| | | 6,593,347 | | Bandarage et al | 07-15-2003 | |
| | | 6,051,588 | | Garvey et al | 04-18-2000 | |
| | | 6,369,260 B1 | | Sanniccolo et al | 04-09-2002 | |
| | | 6,512,137 B1 | | Del Soldato et al | 01-28-2003 | |
| | | 6,323,234 | | Garvey et al | 11-27-2001 | |
| | | 6,482,846 | | Garvey et al | 11-19-2002 | |
| | | 6,410,791 B1 | | Del Soldato | 06-25-2002 | |
| | | 6,573,252 B1 | | Del Soldato | 06-03-2003 | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials ¹ | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|-----------------------------------|--------------------------|-------------------------|---------------------|--------------------------------------|--|--|--|----------------|
| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| | | WO | 94/04484 | | Matji et al | 03-03-1994 | | |
| | | WO | 94/12463 | | Arena et al | 06-09-1994 | | |
| | | WO | 95/09831 | | Del Soldato | 04-13-1995 | | |
| | | WO | 95/30641 | | Del Soldato | 11-16-1995 | | |
| | | WO | 96/32946 | | Garvey et al | 10-24-1996 | | |
| | | WO | 97/31654 | | Del Soldato | 09-04-1997 | | |
| | | WO | 98/09948 | | Del Soldato | 03-12-1998 | | |
| | | WO | 99/45004 | | Del Soldato | 09-10-2000 | | |
| | | WO | 00/06585 | | Del Soldato | 02-10-2000 | | |
| | | WO | 00/25776 | | Bandarage et al | 05-11-2000 | | |

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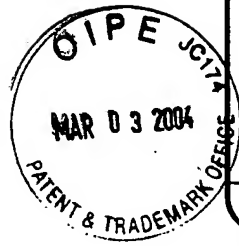
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet | 2

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| Application Number | 10/718,060 |
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Attorney Docket Number | 102258.157 US1

U.S. PATENT DOCUMENTS

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| | | Office ³ | Number ⁴ | Kind Code ⁵ (If known) | | | | |
| | | WO | 01/00563 | | Benedini et al | 01-04-2001 | | |
| | | WO | 01/04082 | | Casraldi et al | 01-18-2001 | | |
| | | WO | 01/10814 | | Benedini et al | 02-15-2001 | | |
| | | WO | 01/12584 | | Del Soldato | 02-22-2001 | | |
| | | WO | 02/051385 | | Trespidi et al | 07-04-2002 | | |
| | | WO | 02/053188 | | Naggi et al | 07-11-2002 | | |
| | | WO | 03/084550 A1 | | Del Soldato | 10-16-2003 | | |
| | | WO | 03/013499 A2 | | Del Soldato | 02-20-2003 | | |
| | | WO | 2004/000781 A2 | | Del Soldato et al | 12-31-2003 | | |
| | | WO | 2004/000300 A1 | | Del Soldato et al | 12-31-2003 | | |

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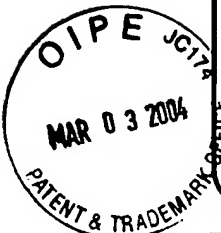
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| Application Number | 10/718,060 |
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| First Named Inventor | Letts et al |
| Group Art Unit | not yet assigned |
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| Attorney Docket Number | 102258.157 US1 |

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| | | Office ³ | Number ⁴ | | | | |
| | | WO | 00/44705 | | Del Soldato et al | 08-03-2000 | |
| | | WO | 00/51988 | | Benedini et al | 09-08-2000 | |
| | | WO | 00/72838 | | Eek et al | 12-07-2000 | |
| | | WO | 00/61537 | | Del Soldato | 10-19-2000 | |
| | | WO | 00/61541 | | Del Soldato | 10-19-2000 | |
| | | WO | 00/61549 | | Del Soldato | 10-19-2000 | |
| | | WO | 00/61604 | | Del Soldato | 10-19-2000 | |
| | | WO | 99/44595 | | Del Soldato | 09-10-1999 | |
| | | WO | 97/16405 | | Del Soldato | 05-09-1997 | |
| | | EP | 0 904 110 | | Del Soldato | 07-24-2002 | |

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Sheet 6 of 9

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|------------------------|------------------|
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|-----------------------|--------------------------|---|----------------|
| | | Wallace et al., Trends Pharamcol., Sci., 15(11): 405-406 (1994) | |
| | | Wallace et al., J. Gastroenterol. Hepatol., 9: S40-S44 (1994) | |
| | | Wallace et al., Novel Molecualr Approacehs to Anti-inflammatory Theory, 121-129 (1994) | |
| | | Wallace et al., Gastroenterol., 106(4), Part 2, A208 (1994) Abstract | |
| | | Wallace et al., Eur. J. Pharmacol., 257:249-255 (1994) | |
| | | Wallace et al., Gastroenterol., 107:173-179 (1994) | |
| | | Reuter et al., Life Sciences, 55(1):1-8 (1994) | |
| | | Reuter et al., Gastroenterol., 106 (4), A759 (1994) | |
| | | Cuzzolin et al, Pharmacol. Res. 29(1): 89-97 (1994) | |
| | | Rachmilewitz et al., Gut, 35:1394-1397 (1994) | |
| | | Conforti et al., Agents Action, 40(3): 176-180 (1993) | |

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Sheet 7 of 9

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|--------------------|-----------------------|---|----------------|
| | | Carty et al., Agents Actions., 39: 157-165 (1993) | |
| | | Cuzzolin et al, Pharmacol. Res. 31: 61-65 (1995) | |
| | | Barrachina et al., Eur. J. Pharmacol., 281: R3-R4 (1995) | |
| | | MacNaughton et al., Life Sciences, 45: 1869-1876 (1989) | |
| | | Kitigawa et al., J. Pharamcol. Exp. Therp., 253: 1133-1137 (1990) | |
| | | Langford et al., Arterioscler. Thromb. Vasc. Biol. 16: 51-57 (1996) | |
| | | Palmer et al., Nature, 333:664-444 (1998) | |
| | | Wallace et al., J. Clin. Invest., 96: 2711-2718 (1995) | |
| | | Konturek et al., Eur. J. Pharmacol., 239:215-217 (1993) | |
| | | Wallace et al., Expert Opinion Inverstigational Drugs, 4(7):613-619 (1995) | |
| | | Boughton-Smith et al., Eur. J. Pharmacol., 191:485-488 (1990) | |

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|-----------------------|--------------------------|---|----------------|
| | | Elliott et al., Gastroenterol., 109: 524-530 (1995) | |
| | | Wallace et al., Eur. J. Pharmacol., 63-68 (1995) | |
| | | Brown et al., Eur. J. Pharmacol., 103-104 (1992) | |
| | | Williams et al., Cancer Research, 61: 3285-3289 (April 15, 2001) | |
| | | Del Soldato et al., Br. J. Pharmacol., 67:33-37 (1979) | |
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**INFORMATION DISCLOSURE
CITATION IN AN
APPLICATION**



(PTO-1449)

ATTY. DOCKET NO.
102258.157 US1

SERIAL NO.
10/718,060

APPLICANT
L. Gordon LETTS et al.

FILING DATE
June 10, 2003

GROUP

U.S. PATENT DOCUMENTS

| EXAMINER'S INITIALS | PATENT NO. | DATE | NAME | CLASS | SUBCLASS | FILING DATE |
|------------------------|--------------|----------|--------------------|-------|----------|----------------|
| | 5,861,426 | 01/19/99 | Del Soldato et al. | | | 03/06/97 |
| | 6,291,523 B1 | 09/18/01 | Fujimoto et al. | | | 08/25/98 |
| | 6,297,260 B1 | 10/02/01 | Bandarage et al. | | | 10/29/99 |
| | 6,593,339 B1 | 07/15/03 | Eek et al. | | | 09/29/00 |
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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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| | December 15, 2003. International Search Report from PCT/US03/18052. |
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